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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA.

Plaintiff,

vs.

NARCO FREEDOM, INC.

Defendant.

Case No. 14-CV-8593

Hon. John G. Koeltl,
U.S.D.J.

**MEMORANDUM OF LAW IN OPPOSITION TO APPLICATION
FOR A PRELIMINARY INJUNCTION**

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PRELIMINARY STATEMENT

This Memorandum of Law is submitted by Defendant Narco Freedom, Inc. (“Defendant” or “Narco Freedom”) in opposition to the application by Plaintiff United States of America (“Plaintiff” or “Government”) for a preliminary injunction in the above-captioned matter.

As detailed herein and in the accompanying expert reports and declaration¹ submitted on behalf of Narco Freedom, the Government is substantially overreaching in its application for a preliminary injunction and its claims in general. More importantly, the Government has failed to meet its burden on this motion to obtain injunctive relief, and its motion should be denied.

Contrary to the Government’s assertions, Narco Freedom’s conduct is not in violation of the Anti-Kickback Statute (42 U.S.C. § 1320a-7b). The housing offered by Narco Freedom is not an “inducement” under the Anti-Kickback Statute. Rather, the housing is offered as an adjunct to the treatment and therapy offered by Narco Freedom, and, in fact, results in better clinical outcomes for its patients than patients who do not have housing.

Additionally, the Government has not met its burden under the standard for obtaining a preliminary injunction. The traditional standard for a court to grant a preliminary injunction includes a showing by Plaintiff that failure to grant the injunction would result in irreparable harm that cannot be remedied with monetary damages. No such showing has been made here. While some courts have held that the Government is relieved of having to prove this traditional element of irreparable harm, it must still consider the other traditionally relevant elements of balancing the equities of the parties and, importantly here, non parties.

¹ Submitted herewith and incorporated by reference as if fully set forth herein are: Expert’s Report of Janet Lerner, PhD, dated November 20, 2014 (“Lerner Rep.”); Expert’s Report of Edward V. Nunes, M.D., dated November 20, 2014 (“Nunes Rep.”); Declaration of Gerald Bethea, , LMHC, CASAC, HSBCP, dated November 20, 2014 (“Bethea Decl.”); and Declaration of Linda J. Clark, dated November 20, 2014 (“Clark Decl.”).

The non-party clients currently served by Narco Freedom and housed in Freedom Houses would be best served if the parties, with consent of the court, could attempt to find a resolution that addresses the Government's concerns and protects the clients while ensuring an effective and financially viable system to deliver services. Any effort to interfere with current operations could jeopardize what are recognized as effective quality services for homeless persons suffering from alcohol and drug addiction, often co-occurring with mental illness.

Moreover, the equities weigh heavily *against* granting the Government's proposed injunction. The impact of the broad injunction that the Government is now seeking would force the closure of Narco Freedom's Freedom Houses and would likely have a cascade effect on other housing providers using the "sober home" model.

Finally, Narco Freedom has made significant changes in recent months to strengthen its corporate governance and compliance capabilities. It has a new CEO with an extensive background and credentials in the area of substance abuse treatment, and its Board of Directors has appointed several new members with a deep and wide range of relevant experience. These changes demonstrate Narco Freedom's commitment to addressing, in good faith, the concerns that the Government has raised.

STATEMENT OF FACTS

I. Narco Freedom's Clinical Services

Narco Freedom and its affiliates care for thousands of addicted persons and their families. Bethea Decl. ¶ 4. Narco Freedom's medically-supervised drug-free outpatient program is a partnership with the criminal justice community that allows for a safe, supervised transition for patients seeking addiction treatment in the community. That program now serves over 3,000 clients, many of whom are referred by branches of the criminal justice system, including the

New York City Department of Probation, New York State Division of Parole, United States Parole Commission, and Brooklyn and Manhattan Drug courts. Bethea Decl. ¶ 5.

Narco Freedom is licensed by the Office of Alcoholism and Substance Abuse Services (“OASAS”) for several services and programs; the Department of Health (“DOH”) as a Public Health Law Article 28 diagnostic and treatment center; and the Office of Mental Health as a Mental Hygiene Law Article 31 mental health clinic. Bethea Decl. ¶ 7. Notably, Narco Freedom most recently received three-year license renewals from OASAS for its chemical dependence outpatient treatment programs, and it has a history of exemplary reviews, including routinely receiving three year license renewals from OASAS. Bethea Decl. ¶ 8 & Ex. C.

II. Narco Freedom’s Provision of Housing to Support Its Substance Abuse Treatment

Before the Court are issues related to Narco Freedom’s long-standing supportive housing resources. These resources are offered to patients who are enrolled in Narco Freedom’s substance abuse programs and lack housing or are directed to Narco Freedom specifically by state agencies such as the New York State Division of Parole. Bethea Decl. ¶ 9.

Narco Freedom’s philosophy has long been that an investment in treatment of substance abuse disorders that does not include transitional housing is wasteful and should be avoided if possible. Narco Freedom’s Freedom Houses, also known as sober or three-quarter homes, were developed as an adjunct effort to bridge the gap created by the extremely modest and insufficient housing assistance provided by Medicaid, which is known universally to be woefully inadequate for a person to secure housing outside a shelter environment. Bethea Decl. ¶ 10.

Experts in the field from governmental agencies such as the National Health Care Counsel for the Homeless, National Institute on Drug Abuse, National Institute on Alcohol Abuse and Alcoholism, U. S. Department of Housing and Urban Development, and many others

have conducted extensive research and studies on the efficacy of substance abuse treatment modalities in the absence of housing resources. By far, the weight of these studies establishes quite clearly the close and unsurprising nexus between housing and success of clinical treatments for substance abusers. Lerner Rep. ¶ 12; *see also* Nunes Rep. ¶ 16, 21-24.

Housing stability is an essential element of successful treatment and recovery. As noted by a leading national homeless services organization, “when combined with supportive services, meaningful daily activity in the community (including work), and access to therapy, appropriate housing can provide the framework necessary to end homelessness for many individuals. Without a stable place to live, recovery often remains out of reach.”²

Narco Freedom’s supportive housing resources are a highly-structured adjunct to its clinical services. Narco Freedom addresses housing needs as part of its treatment planning with its patients, using OASAS-approved intake forms. The intake forms address, among other things, the type, duration, adequacy and social and environmental conditions of the patient’s current housing, or lack thereof. Thus, housing issues (along with other issues) are considerations only after a person has been admitted into the clinical program and approved for treatment. Lerner Rep. ¶ 21; Bethea Decl. ¶ 13-14. Narco Freedom’s treatment-with-housing approach is an important component of Narco Freedom’s clinical service delivery model and has yielded recovery rates that are greater than programs that fail to actively address housing needs during recovery. Lerner Rep. ¶ 16; Bethea Decl. ¶ 13-15; *see also* Nunes Rep. ¶ 22-24.

This model is a form of contingency management, which has been thoroughly researched and demonstrated to be one of the most effective treatment strategies for substance dependence. Drug courts and related programs make participation in treatment, and progress in treatment (i.e.

ceasing drug use and making other positive changes) a requirement to stay out of jail. These can all be viewed as examples of contingency management. Nunes Rep. ¶ 19.

Narco Freedom's housing is closely coordinated with the clinical services provided and is managed, secured and monitored by Narco Freedom staff. This strategic investment in housing is an adjunct to the clinical services provided and is by clinical and financial necessity, only available to patients who qualify for treatment through the intake process and affirmatively seek assistance with housing to avoid homelessness, or at the affirmative direction of the State via orders issued by the New York State Division of Parole. Bethea Decl. ¶ 14.

Narco Freedom's commitment to the provision of its supportive housing resources to patients comes, however, at a significant cost and has required an extensive financial, administrative, and managerial commitment from Narco Freedom to its patients. Given the unavailability of funding from OASAS or other sources for housing costs, some of these housing costs are necessarily born by Narco Freedom, which treats this commitment to housing as an important aspect of its delivery of clinical services. Even with dwindling reimbursement from the State, Narco Freedom does a lot with a little, thereby enabling it to invest in its adjunct housing services that are carefully coordinated and designed to be integrated with its clinical programs. Bethea Decl. ¶ 18.

It would be impractical and a financial impossibility for Narco Freedom to serve as a housing resource for other substance abuse providers, as demanded by the Plaintiff. This would defeat the clinical benefits and significance of the close coordination between supportive housing resources and clinical services. Bethea Decl. ¶ 19.

² NCH Fact Sheet #6, Addiction Disorders and Homelessness, Nat. Coalition for the Homeless (Aug. 2007), available at <http://www.nationalhomeless.org/publications/facts/addiction.pdf>. Lerner Rep. ¶ 14.

Additionally, the loss of coordination of clinical services and housing arrangements would result in inefficiency, and potentially dangerous and unstable conditions at the Freedom Houses that would warrant their closure. For example, it would not be possible for Narco Freedom to manage, track and coordinate the treatment of individuals being treated at other programs, or who may suffer from mental or health conditions that could put others at risk. Lerner Rep. ¶ 16, 23, 26, 30; Bethea Decl. ¶ 20.

The Government's suggestion that Narco Freedom should move to a Community Residential Services ("CRS") model is not tenable. The CRS housing model has exacting staffing requirements that would significantly increase the costs of running the facility. Lerner Rep. ¶ 35. The CRS housing is more expensive and would necessitate a tremendous influx of money in both operational staffing and alterations to the Freedom House buildings. Lerner Rep. ¶ 36.

The Government's proposal, which seeks to render Narco Freedom a housing provider rather than a substance abuse provider, is not a viable practical, economic or clinical model and is certainly not in the best interests of its patients. Lerner Rep. ¶ 37; Bethea Decl. ¶ 21.

III. Investigations by the State and Federal Government

Since 2012, the U.S. Attorney's Office has conducted a joint investigation with the Office of the Inspector General for the United States Department of Health and Human Services focusing on, among other things, potential violations of the Federal Anti-Kickback Statute related to Narco Freedom's operation of its Freedom Houses. Declaration of Sue O'Connor ¶ 2 (ECF Doc. No. 11); Clark Decl. ¶ 24. Narco Freedom cooperated with the investigation by responding to Civil Investigative Demands issued by the United States. Clark Decl. ¶ 25. For "well over a year now" the N.Y. Attorney General ("AG") has conducted its own investigation,

focusing on allegedly criminal conduct by former Narco Freedom personnel and other areas that reportedly overlap with the investigation by the United States. Transcript, Hearing on United States' Mot. for Prelim. Injunction at 9-10 (Oct. 29, 2010) (ECF Doc. No. 15); Clark Decl. ¶ 26.

IV. Governance Changes by Narco Freedom

In late July 2014, Narco Freedom CEO Alan Brand resigned that position, and he currently has no role with Narco Freedom. Gerald Bethea, LMHC, CASAC, HSBCP, with an extensive background and credentials in the area of substance abuse treatment, was appointed as Acting CEO and later named CEO. Clark Decl. ¶ 27. Narco Freedom undertook a series of steps to strengthen its corporate governance and compliance capabilities, appointing new members to its Board of Directors and entering into a compliance and consulting agreement with The Bonadio Group, Inc. Clark Decl. ¶ 29.

PROCEDURAL HISTORY

I. The Instant Action

Plaintiff commenced this action on October 28, 2014 and the following day sought a TRO to prohibit Narco Freedom from removing any Freedom House resident for failure to attend a Narco Freedom outpatient program. The parties negotiated a modified order, which the Court granted. The parties subsequently agreed to an extension of the briefing schedule and hearing on instant motion for a preliminary injunction, and the Court granted that request. After continued negotiations, Narco Freedom requested a further extension, expedited but limited discovery, and an informal conference pursuant to Local Civil Rule 37.2.

II. State Proceedings

On October 22, 2014, the AG indicted former Narco Freedom C.E.O. Alan Brand, his son and former Narco Freedom C.I.O. Jason Brand, Daso Development Corp. and Narco Freedom on

various allegations unrelated to Narco Freedom's status as a provider of substance abuse related services. Clark Decl. ¶ 32. Jason Brand had already resigned his position, and Alan Brand subsequently resigned as a member of Narco Freedom. Clark Decl. ¶ 32.

On October 29, 2014, the AG commenced an action in the Supreme Court of New York, Bronx County seeking a receiver and moved for a TRO. The Honorable Fernando Tapia denied the AG's motion, holding that there was no emergency. Clark Decl. ¶ 33.

Despite the Supreme Court's denial of the AG's application for a TRO – in support of which OASAS had submitted an affidavit by its General Counsel – OASAS notified Narco Freedom that it intended to appoint a temporary operator, based largely on the investigations and proceedings brought by the AG and United States Attorney. Narco Freedom met with OASAS to discuss the proposed agency action and subsequently submitted voluminous documentation. Based on Narco Freedom's cooperation, OASAS agreed to hold in abeyance its intention to establish a temporary operator pending further review. Clark Decl. ¶ 34.

ARGUMENT

I. The Government Has Not Met the Standard for Obtaining a Preliminary Injunction.

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. NRDC, Inc.*, 555 U.S. 7, 24 (2008). When the Government seeks injunctive relief pursuant to 18 U.S.C. § 1345, it is required to "demonstrate that 'probable cause' exists to believe that the defendant is currently engaged or about to engage in a fraudulent scheme" violative of an applicable statute. *U.S. v. William Savran & Assoc.*, 755 F. Supp. 1165, 1177 (E.D.N.Y. 1991).

Moreover, "[i]njunctive relief is authorized under section 1345 only when the alleged fraudulent scheme is ongoing and there exists a threat of continued perpetration; the statutory equitable remedy is not available for solely past violations." *Id.* at 1178. While "a showing that

a scheme has been carried out in the past, even in the recent past, is relevant to the determination of the probability that such a scheme will be perpetrated in the future,” such a showing “is not dispositive when other circumstances indicate that there is little danger that the scheme will continue into the future.” *Belden*, 714 F. Supp. at 45-46.

Additionally, while some courts have held that the Government need not prove irreparable harm to obtain an injunction under § 1345, it is still proper and necessary for the court to consider other elements traditionally relevant to an application for injunctive relief – including a balancing of the equities and relative hardships of both the parties and non-parties. *See, e.g., SEC v. Management Dynamics, Inc.*, 515 F.2d 801, 808 (2d Cir. 1975) in which the Court stated that, while the requirement of demonstrating irreparable harm may be relieved:

We scarcely mean to imply that judges are free to set to one side all notions of fairness because it is the [Government], rather than a private litigant, which has stepped into court. The [statutes providing for injunctive relief by the Government] hardly evidence a Congressional intent to foreclose equitable considerations by the district court...And, as we said in *SEC v. Manor Nursing Centers, Inc.*, 458 F.2d 1082, 1102 (2d Cir. 1972), “in deciding whether to grant injunctive relief, a district court is called upon to assess all those considerations of fairness that have been the traditional concern of equity courts.”

See also SEC v. Electronics Warehouse, Inc., 689 F. Supp. 53, 70 (D. Ct. 1988) (“Although the securities injunction is a ‘creature of statute,’ a court may appropriately consider equitable factors in exercising its discretion to grant or deny such an injunction. Thus, the court may assess all those considerations of fairness that have been the traditional concern of equity courts”); *Great Earth Int’l Franchising Corp. v. Milks Devs., Inc.*, 302 F. Supp. 2d 248, 252 (SDNY 2004) (“[I]n assessing the balance of hardships between plaintiff and defendant, the court must also consider potential harm to the non-parties.”)

The Second Circuit in *Manor Nursing Centers, Inc.*, held that in considering whether or not to grant the Government an injunction “...the adverse effect of an injunction upon defendants is a factor to be considered by the district court in exercising its discretion.” 458 F.2d at 1102; *see also, e.g., Tuccillo v. Geisha NYC, LLC*, 635 F. Supp. 2d 227, 247 (E.D.N.Y. 2009) (risk that a party’s business may be destroyed demonstrates a balance of hardship in favor of that party).

As set forth herein, the Government has failed to meet its burden. The Government has failed to demonstrate that probable cause exists to believe that Defendant is currently engaged in a fraudulent scheme. Moreover, the equities weigh heavily in favor of denying the Government’s application in this matter. The negative impact of the broad injunction on Narco Freedom and the public who benefit from its services, as well as similar “sober housing” and other holistic models, would be tremendous, as described in more detail in section I.B.2 below.

A. Narco Freedom’s Conduct Does Not Violate the Anti-Kickback Statute.

1. Housing is not an “inducement” under the Anti-Kickback Statute.

The Government inaccurately asserts that Narco Freedom’s provision of low cost housing is an illegal inducement prohibited by the Anti-Kickback Statute. To prove a violation of the Anti-Kickback Statute, the government must establish that the defendant (1) knowingly and willfully (2) gave, received, or solicited a remuneration (3) in return for patient referrals (or other business) (4) in connection with a federal health care program. Importantly, the case law with respect to the first three of those four elements varies across United States federal jurisdictions. This is precisely the climate that should warrant extra caution from the Courts, particularly where considerable harm will result to the subject Defendant and the communities it serves.

As set forth more fully below, providing housing to clinical patients as an adjunct to therapy does not constitute “remuneration” under the statute. Additionally, Narco Freedom did

not establish its Freedom Houses to improperly induce patients to seek treatment at Narco Freedom Clinics.

(i) *Low Cost Housing as an Adjunct to Therapy is Not Remuneration.*

Narco Freedom has not offered or provided remuneration to Medicaid beneficiaries. The provision of housing to clinical patients in exchange for their monthly public housing allowance (\$215) is not remuneration, particularly in the circumstances that are present here.

Narco Freedom recognized that housing in New York City is nearly impossible with the funds currently provided to the neediest members of our communities and that its patients' clinical outcomes were suffering because of homelessness. As a result, it decided to address that need by offering temporary housing to clinical patients as an adjunct to their treatment program. The intended purpose of the provision of housing was to improve clinical outcomes and overall access to necessary care. Bethea Decl. ¶ 11. Notably, this primary goal was achieved and clinical outcomes have significantly improved. Lerner Rep. ¶ 16; Bethea Decl. ¶ 12.

The Government relies on a Second Circuit decision which recognizes that the Anti-Kickback Statute applies to payments made directly to beneficiaries. The Government jumps to the conclusion that Narco Freedom's practice of allowing Medicaid recipients using Narco Freedom's outpatient services to reside in a Freedom House is sufficient to satisfy the remuneration requirement in the Anti-Kickback Statute. In that decision, *United States v. Aginsky*, 165 F.3d 15 (2d Cir. 1998), however, the court affirmed the conviction of a defendant who provided "cash and household items" to recipients in exchange for their agreement to accept certain medical equipment. There, the equipment provided was not medically necessary and wasted federal monies. Here, the housing provided by Narco Freedom met a community need and enhanced access to drug treatment services.

In further support of this argument, Narco Freedom respectfully requests the Court to consider last month's proposal by the Office of Inspector General to revise both the Anti-Kickback Statute safe harbors and the civil monetary penalty rules to incorporate and implement the recent Affordable Care Act-mandated exceptions to the definition of "remuneration." *See* Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing, 79 Fed. Reg. 59717 (October 3, 2014) (proposing amendment to 42 C.F.R. pts. 1001 & 1003). Among the changes, the OIG would extend protection to certain forms of remuneration (patient incentives and inducements) that promote access to care and pose a low risk of harm to patients and to federal health care programs, and also to certain remuneration provided to financially needy individuals. *Id.*

The OIG proposed to define "promotes access to care" as remuneration that improves a beneficiary's ability to access medically necessary health care items and services. *Id.* The OIG is also considering expanding this definition to include remuneration that has an indirect connection by encouraging, supporting and/or assisting patients in accessing care, or making access to care more convenient for patients. *Id.* Remuneration would be deemed to pose a "low risk of harm" if it (1) is unlikely to interfere with or skew clinical decision-making; (2) is unlikely to increase costs through overutilization or inappropriate utilization; and (3) does not raise patient-safety or quality-of-care concerns. *Id.* Another proposed exception to the definition of "remuneration" concerns the offer or transfer of items or services (not including cash or instruments convertible to cash) for free or less than fair market value for individuals determined to be in financial need. Based on the October 3, 2014 publication, these proposed changes "are intended to protect certain arrangements that offer beneficiaries incentives to engage in their

wellness or treatment regimens or that improve or increase beneficiary access to care, including better care coordination.” *Id.*

Although the OIG just recently proposed these implementing regulations, it seems to have incorporated them into prior advisory opinion analyses. In Advisory Opinion 11-01 (posted Jan. 10, 2011), the OIG considered these new ACA exceptions to remuneration when it advised that it would not take action against a network of pediatric charity hospitals for providing, among other things, lodging and transportation to patients and their families who demonstrate a financial need. *See* OIG Advisory Opinion 11-01 (issued Jan. 3, 2011, posted Jan. 10, 2011). Therein the OIG acknowledged the new ACA exceptions and noted that the inducement prohibition does not apply to “remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under regulations).” *Id.* At that time, no regulations had been promulgated, or even proposed.

Narco Freedom provides the low cost housing option to its patients as an adjunct to their clinical therapy to help pave the way for a successful recovery. This promotes the resident’s access to care since the resident patients are relieved of the incredible concern of homelessness. The government itself asserts that Narco Freedom was providing services to underserved communities and meeting a need that has not otherwise been effectively met. Lerner Rep. ¶ 24; Bethea Decl. ¶ 15, 18. The provision of low cost housing poses a very low risk of harm as it would not impact clinical decision making, increase costs (the patients are already patients of Narco Freedom’s clinical treatment programs) and certainly would not create safety or quality of care concerns (in fact it would minimize them compared to the alternative - homelessness).

Consistent with the above, the provision of low cost housing to clinical patients at Narco Freedom is not remuneration under the Anti-Kickback Statute.

(ii) *Narco Freedom Did Not Offer Housing to Patients to Induce Increased Medicaid Referrals.*

The plain language of the Anti-Kickback Statute is extremely broad. As a result, there has been disagreement among courts with respect to the proper standard to be implemented when determining the scope of the statute (i.e. what conduct constitutes an illegal inducement). There appear to be two principal tests applied, the “one purpose test” and the “primary purpose test,” however, several courts have applied the tests in a modified fashion thereby creating what appears to be a continuum of tests based on the facts of the subject case.

The Government’s proposition that the “one purpose test” applies in this case is erroneous as neither the Second Circuit nor the U.S. Supreme Court has formally adopted a standard. While the Second Circuit recently affirmed a District Court’s jury instructions consistent with the “one purpose test,” that decision also upheld the further requirement that the prosecution prove “the remuneration was offered or paid as a quid pro quo in return for the referring of the patient.” *United States v. Krikheli*, Nos. 11-2865-CR (L), 11-2869-CR (CON), 461 F. App’x 7, 11 (2d Cir. Feb. 2, 2012). This further requirement adds an element of significance to the intended purpose that more closely aligns with the “primary purpose test” and would limit the breadth of the “one purpose test.” Narco Freedom respectfully submits that a test similar to the “primary purpose test” is the appropriate test for this district and circuit.

The “one purpose test,” first announced by the Third Circuit in *U.S. v Greber*, holds “if one purpose of the payment was to induce future referrals, the Medicare statute has been violated.” *U.S. v. Greber*, 760 F.2d 68, 69 (3rd Cir. 1985), cert. denied, 474 U.S. 988 (1985). Note, however, the *Greber* case, like many others that have tended to follow its general proposition, involved facts wholly distinguishable from the facts in this case. Most, if not all, of the landmark cases that apply that test (or a version thereof) involved defendants whose conduct

fell within the traditional, straightforward kickback arrangements the government sought to eradicate with the statute (monetary compensation in exchange for referrals). *See, e.g., United States v. Borrasi*, 639 F.3d 774 (7th Cir. 2011) (kickbacks to a group of physicians in return for referrals to psychiatric hospital); *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000) (monetary remuneration in exchange for referrals); *United States v. Davis*, 132 F.3d 1092 (5th Cir. 1998) (payments from physician to induce Medicare referrals); *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989) (physician compensation included component to induce referrals); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985) (physician accepting monetary kickbacks for referring patients). Frequently, the defendants sought to legitimize this conduct by layering or integrating the blatant monetary kickback with legitimate compensation for services to then argue (under the primary purpose rule) that their compensation was not in violation of the statute. As a result, Courts were left with no choice but to implement a “one purpose” type standard. That is simply not the case here.

Furthermore, while many courts and the OIG have adopted the “one purpose test,” careful review of those decisions reveals unique attempts to narrow its extremely broad effect. For instance, in *U.S. v. Kats*, the Ninth Circuit adopted the *Greber* interpretation, but in applying the “one purpose test” the Court concluded that when a payment is not incidental to the delivery of healthcare services or goods, the statute is violated. *United States v. Kats*, 871 F.2d 105. Likewise, the court’s instruction in that case had a subtle distinction and established that when remuneration is merely incidental to a patient’s care and treatment, there is no violation. Notably, this would be consistent with the facts here where the alleged remuneration (housing) was merely an incidental benefit provided to Narco Freedom’s clinic patients (when available).

The Tenth Circuit also adopted the *Greber* “one purpose test” but with an important caveat. In *U.S. v McClatchey*, the Tenth Circuit upheld the trial court’s instruction to the jury that the defendant “cannot be convicted merely because [he] hoped or expected, or believed that referrals may ensue from remuneration that was designed wholly for other purposes.” *United States v. McClatchey*, 217 F.3d at 834-35 (“[A] hospital or individual may lawfully enter into a business relationship with a doctor and even hope for or expect referrals from that doctor, so long as the hospital is motivated to enter into the relationship for legal reasons entirely distinct from its collateral hope for referrals”). At most, that is what occurred here. Narco Freedom developed the housing component of its therapy to increase the success of its treatment programs. A tangential benefit certainly should not deter such a rewarding program component.

The more appropriate standard for Anti-Kickback Statute is the “primary purpose test,” created when the First Circuit declined to adopt the “one purpose rule” in *United States v. Bay State Ambulance and Hosp. Rental Serv., Inc.*, 874 F.2d 20 (1st Cir.1989). Instead, the court upheld the District Court’s instruction to the jury that the “primary purpose” must be improper in order to obtain a conviction under the statute. *Id.* at 32. The Court went on to instruct the jury that it could not convict if the jury found that the improper purpose behind the payments was an “incidental or minor one.” *Id.* at 29 - 30. In affirming the decision, the First Circuit specifically discussed, but chose not to adopt, the *Greber* test. This Court should do the same.

Regardless of the test adopted and applied in this case, Defendant Narco Freedom did not, in whole or in part, intend to improperly induce Medicaid referrals. Rather, housing was offered in an effort to further its patients’ chance for successful completion of treatment programs. Bethea Decl. ¶ 10- 14. The mere fact that the provision of housing may have

attracted more patients to attend Narco Freedom's clinical treatment program, as opposed to another clinic, is insufficient to establish an Anti-Kickback Statute violation here.

B. The Equities of Granting an Injunction are Far Outweighed by the Impact on Defendant and Numerous Non-Parties.

As discussed above, in deciding whether to grant an injunction, the Court should assess all considerations of fairness, including the potential adverse effects of an injunction on the defendant and non-parties. In this case, the broad injunction sought by the Government would destroy Narco Freedom's treatment model, would likely require Narco Freedom to close its Freedom Houses, would leave Narco Freedom's patients in limbo, and would likely have a wide-reaching impact on other sober living and holistic treatment programs.

1. Narco Freedom's Current Service Delivery Model Plays a Vital Role in Addressing the Needs of Patients At Risk of Homelessness.

The connection of Narco Freedom's treatment program with residence in a Freedom House is a vital component of treatment for many patients. The model is supported by scientific research and is proven by the results obtained by Narco Freedom. Nunes Rep. ¶ 19-24; Lerner Rep. ¶ 13-15; Bethea Decl. ¶ 16-19. The Freedom Houses provide patients with a safe and monitored environment. By offering residency in a Freedom House to qualified individuals who are enrolled in Narco Freedom's treatment programs, Narco Freedom is able to ensure that the patients are following through with their treatment, that already at-risk individuals are properly monitored, and that basic rules and structures are in place to prevent, or at least limit, the patients from engaging in negative conduct. Bethea Decl. ¶ 15.

2. Granting the Preliminary Injunction Would Destroy the Ability of Narco Freedom – and Other Sober Home Operators – to Serve This Vulnerable Client Base.

The injunction sought by the Government would destroy that holistic treatment program. By seeking to force Narco Freedom to eliminate the treatment/housing connection, the Government would transform the Freedom Houses from an effective adjunct to the treatment of addiction to just another place for at-risk individuals to congregate. Lerner Rep. ¶ 32.

Moreover, without the ability to properly monitor residents, Narco Freedom could not safely or effectively operate the Freedom Houses and would be forced to close them down. Not only would this eliminate the availability of housing for numerous patients, it would also eviscerate the core of the treatment program. Bethea Decl. ¶ 19-20. Forcing Narco Freedom to eliminate its treatment plus housing model is not medically responsible or supportable. The Government has presented no scientific evidence in support of its motion. Narco Freedom has provided abundant factual and medical evidence showing that it provides the best possible means for patients to have a successful outcome. Nunes Rep. ¶ 19-24; Lerner Rep. ¶ 12-23.

Additionally, the Government's suggestion that Narco Freedom should move to a Community Residential Services model or some other model is not tenable and simply shows that the Government is not the proper party to determine the service model that Narco Freedom should provide. Lerner Rep. ¶ 35-36.

The injunction sought by the Government would also be the proverbial "shot across the bow" for similar sober living and holistic treatment programs. If the Government is able to dismantle the Narco Freedom treatment plus housing model, similar programs throughout the country would be on notice and in jeopardy of suffering the same fate. Fear of the Government could reasonably cause valuable holistic treatment programs to either shut down entirely or modify their programs in a manner that is not as effective and beneficial for the patients.

In sum, the negative impact of granting the Government’s injunction is substantial. It would significantly damage Narco Freedom’s entire treatment program and thereby directly impact the patients enrolled in Narco Freedom’s program, which, ultimately, would impact the public at large. On the other hand, denying the injunction and maintaining the *status quo* while this matter is pending a full and final determination carries little risk and negligible negative impact on any party, Narco Freedom’s patients, and the public at large. Thus, the Court should deny the Government’s application for a preliminary injunction.

II. The United States Improperly Seeks to Regulate an Area Traditionally Left to the States

Where Congress has legislated in a field traditionally occupied by the states, “the assumption [is] that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” *See Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Indeed, health care and public safety regulation is an area traditionally regulated by the states as a matter of “local concern.” *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 661 (1995). Thus, unless Congress has made an intention to supplant State law “clear and manifest,” the assumption is that the area has been left to the states. *See Bates v. Dow Agrosiences LLC*, 544 U.S. 431, 449 (2005) (“In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention clear and manifest.” (internal quotation marks omitted)). Here, there is nothing in the Anti Kickback Statute that demonstrates a “clear and manifest” intention by Congress to regulate substance abuse service providers.

Indeed, the Second Circuit has recognized that the False Claims Act in the context of Anti Kickback Statute violations does not preempt state regulatory authority and thus is not a

means to infringe upon a state's police power to regulate public health. *See United States v. Quest Diagnostics, Inc.*, 734 F.3d 154, 163 (2d Cir. 2013). The court reasoned, "[n]othing in the False Claims Act evinces a clear legislative intent to preempt state statutes and rules . . .") *Id.* *See also United States ex rel. Doe v. X. Corp.*, 862 F. Supp. 1502, 1507 (E.D. Va. 1994) (emphasis supplied) ("[w]hile the [FCA] permits any person . . . to bring a qui tam suit, it does not authorize that person to violate state laws in the process.")

While this action is not a *qui tam* proceeding, the Second Circuit's rationale behind its decision in *Quest Diagnostics* is equally applicable to what the Government seeks to do here. The instant matter is simply an indirect attempt to usurp New York State's police power to regulate health care and public safety through an overly-broad interpretation of the Anti-Kickback Statute. The Government's position is essentially that since New York State has elected not to regulate three quarter homes, such as the Freedom Homes at issue, it is free to exercise regulatory power through a judicial proceeding based upon federal statutes. It cannot. There is nothing in the statute that indicates the federal government intended to preempt the arena of health and public safety from the states, much less any indication it could be used to regulate three-quarter houses such as the Freedom Houses operated by Narco Freedom.

Moreover, even though the State has not legislated or promulgated a regulatory framework governing three quarter houses, its involvement and intent to regulate this area is readily apparent. The New York State Department of Corrections and Community Supervision ("DOCCS"), from whom a significant portion of Narco Freedom's clientele has originated, has stringent regulations for Narco Freedom to remain an approved contractor for its Community Based Residential Programs. For example, Narco Freedom's contract with DOCCS clearly sets forth that "[t]he Contractor shall furnish the necessary facilities, equipment, and personnel to

provide for the safekeeping, care and assistance of persons residing in facilities as required by DOCCS.” Bethea Decl. Ex. B. The contract further contains strict regulations and requirements about the personnel, conditions of the facility, referrals and performance measures. *Id.* It therefore is evidence of the state’s regulation of the Freedom Homes and a demonstration of police power that the Government cannot supersede.

In addition, OASAS has designated Narco Freedom as an approved provider of services for “supportive housing,” although it is not licensed as such an entity. Bethea Decl. ¶ 7. This is additional evidence of New York State’s implicit regulation of facilities like Narco Freedom.

The Government has also implicitly recognized the authority of the state to regulate in this area by stating that it will not prosecute state-regulated housing such as the OASAS-certified Community Residential Services housing. Clark Decl ¶ 31. The Government therefore must similarly defer to the state with respect to other housing models and such as the sober homes and with respect to the partnerships that Narco Freedom has successfully engaged in with DOCCS, Parole and other New York State law-enforcement agencies.

This attempted federal encroachment poses a significant threat to the State. The federal government is attempting to not only regulate but shut down action that is condoned by the State. Programs that would be affected in the event the injunction were granted include HIV/AIDS Services Administration homes run by Narco Freedom and many other providers, scatter site housing, supportive housing, parole programs and drug court referrals. By the Government’s logic, the requested relief could even result in liability attaching to charitable organizations raising funds for local housing programs that the federal government disapproves of. The Government’s broad interpretation of the Anti Kickback Statute as a means to regulate three-quarter houses and deny a patient access to an in-house service/benefit that is direct and critical

benefit to substance abuse patients is a violation of the separation of powers doctrine and New York's ability to regulate such facilities. Accordingly, the Court should not permit the effort by the Government to obtain "judicial legislation" over an area of traditional state police power.

III. The Government Failed to Name OASAS, a Necessary Party, in this Action

Tellingly, the Government does not object to the provision of housing services by substance abuse providers so long as they are regulated by OASAS. Yet the Government takes the position that the lack of state regulation for three quarter homes somehow causes the provision of temporary emergency housing to become a kickback. Should the Government be successful in its claim for an injunction based on this theory, it would certainly affect providers of other types of housing such as supportive housing and scatter housing under OASAS. The Government's use of this proceeding as a "test case" will likely have far-reaching implications for the providers OASAS endorses and the individuals it serves. Accordingly, Narco Freedom submits that OASAS is a necessary party to this proceeding pursuant to Fed. R. Civ. P. 19(a).

Fed. R. Civ. P. 19(a) deems a party necessary or "required" if he or she is "one whose participation is so desirable or important that the party must be joined so long as she or he is 'subject to service of process' and joinder 'will not deprive the court of subject-matter jurisdiction.'" *Marvel Characters, Inc. v. Kirby*, 726 F.3d 119, 131 (2d Cir. 2013) (quoting Fed. R. Civ. P. 19(a)(1)). A party must be joined if (1) in that person's absence, the court cannot accord complete relief among existing parties; or (2) that person claims an interest relating to the subject of the action and is so situated that disposing of the action in the person's absence may (a) as a practical matter impair or impede the person's ability to protect the interest; or (b) leave an existing party subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations because of the interest. Fed. R. Civ. P. 19(a)(1).

Here, the Court cannot provide complete relief to the Government without joining OASAS. Narco Freedom's operation is regulated by OASAS, and Narco Freedom is licensed through OASAS. The injunction that the Government seeks cannot be implemented without OASAS' review of Narco Freedom's license and continued operation. However, joinder is not feasible because the 11th Amendment provides that the State is immune from suits in federal court for declaratory and/or injunctive relief. Where, as here, a necessary party cannot be joined, the Court must determine if the action should proceed among the parties before it, or should be dismissed, the absent person being regarded as indispensable. Fed. R. Civ. P. 19(b).

The four factors for the Court to consider when determining whether to proceed or dismiss the action are: (1) whether judgment rendered in the party's absence might prejudice it or parties to the action; (2) the extent to which any prejudice could be alleviated; (3) whether a judgment in the party's absence would be adequate; and (4) whether the plaintiff would have an adequate remedy if the court dismissed the suit. Fed. R. Civ. P. 19(b)(1-4).

The Court is free to determine the weight of each consideration according to the circumstances of each case. *Fluent v. Salamanca Indian Lease Auth.*, 928 F. 2d 542, 548 (2d Cir. 1991). However, where a necessary party is immune from suit there is "very little room for balancing of other factors set out in Rule 19(b), because immunity may be viewed as one of those interests compelling by themselves." *Id.*

A state's immunity can warrant dismissal even where a plaintiff is left without an adequate remedy. *Seneca Nation of Indians v. New York*, 383 F. 2d 45 (2d Cir. 2004). Here, there is an adequate remedy if the court dismisses the suit, however, because the State of New York can be sued in state court. Fed R. Civ. P. 19(b)(4).

Even if the fourth factor did not warrant strongly in favor of dismissal, the first three factors weigh in favor of dismissal as well. Both OASAS and Narco Freedom will be prejudiced if a Judgment is rendered because any injunction will affect the relationship between OASAS and Narco Freedom without any input from OASAS. Further, this prejudice could only be alleviated by naming the State as a party. Finally, a Judgment in OASAS' absence will not be adequate because the only relief that the Government seeks is the complete relief that makes OASAS a necessary party. Therefore, the Court must dismiss this case for the Government's failure to name a necessary and indispensable party.

CONCLUSION

Accordingly, for all the reasons stated above and in the accompanying expert reports and declarations, the Court should deny the Government's application for a Preliminary Injunction.

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